

REMARKS

Claims 18, 19 and 36 are currently pending and considered in the application. Claims 1-17, 20-35 and 37-104 claims have been withdrawn. Proposed amendments are made to Claim 18 in the present response. Support for the proposed amendments are found throughout the present application, for example at Paragraph [0053]. By the amendments, applicant does not acquiesce to the propriety of any of the Examiner's rejections and does not disclaim any subject matter to which Applicant is entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

I. Claim rejections under 35 U.S.C. § 103

Claims 18, 19 and 36 are rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Leung et al, U.S. Patent No. 6,596,298, ("Leung") in view of Hang, U.S. Patent Publication No. 2007/0184093, ("Hang") and Chobanian, U.S. Patent No. 6,139,847 ("Chobanian"); or over Hang in view of Chobanian. OA, page 2.

The Examiner, argues that Leung "teach edible films that preferably include pullulan...the film more preferably comprises pullulan as a film forming agent in amounts of 45% to 70% ." OA, page 2. Regarding Hang, the Examiner argues that " Hang teaches soluble films comprising a soluble polymer and a strengthening polymer (0017) for delivery of emergency medical care active agents such as nitroglycerin (0019). For the soluble films, Hang preferably teaches pullan (0030)." OA, page 2. The Examiner thus concludes "that it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to incorporate nitroglycerin in the fast dissolving oral film containing pullulan of Leung or Hang because both Leung and Hang teach pullulan films for fast dissolution and for the delivery of oral active agents and Hang particularly teaches the films for nitroglycerin delivery. Further, a skilled artisan would have been able to employ combinations of medicaments for treating cardiovascular conditions with an expectation to at least achieve an additional protective effect if not a synergistic effect, as suggested by Chobanian et al (abstract, col. 3-4)." OA, page 3. Applicant respectfully traverses.

To maintain a proper rejection under 35 U.S.C. § 103, the Examiner must meet four conditions to establish a *prima facie* case of obviousness. First, the Examiner must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed

composition or device or carry out the claimed process. Second, the Examiner must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Examiner must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966). 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

Solely in the interest of advancing prosecution, and without agreeing with the propriety of the Examiner's rejection or disclaiming any subject matter to which they are entitled, Applicant has proposed amending claim 18 to state as follows (additions underlined):

A consumable film comprising about 0.01 mg to about 100 mg nitroglycerin adapted to dissolve in the mouth of a patient, wherein said film comprises nitroglycerin in a single layer including pullulan and at least one additional pharmaceutical agent, and wherein said consumable film is rapid-dissolving and provides rapid transmucosal delivery of nitroglycerin to a patient.

Leung does not teach or suggest any range or amount of nitroglycerin. Hang and Chobanian do not make up for this deficiency. Accordingly, Leung in view of Hang and Chobanian or Hang in view of Chobanian, do not teach each and every limitation as presently claimed.

Further, regarding the Examiner's arguments, the Examiner's characterization of Hang and corresponding conclusions are factually inaccurate and wrong as a matter of law. First, the Examiner does not show any teaching, suggestion or motivation to combine Hang with Leung. The Examiner argues that Hang teaches "fast dissolution" and "quick dissolution and oral delivery of nitroglycerin." OA, page 3. The Examiner misses the overall teachings of Hang, *i.e.*, the strengthening of soluble films by making them less water soluble -- which

inherently makes the films less dissolvable. Indeed, the overall teaching of Hang relates to adding strengthening polymers that "decrease the water solubility and total soluble matter of the end product" (*see, e.g.*, Paragraph [0033]), wherein "low solubility is required for slow release and longer dissolving time applications." Paragraph [0037]. Although Hang discusses various ratios of "soluble polymer" and "strengthening polymer," the overall teachings of Hang relate to adding strengthening polymer to strengthen the thin film and deter the rapid dissolution of the film. Accordingly, there is no teaching, suggestion or motivation to combine the dosage form of Hang, a less soluble dosage form that deters rapid dissolution, with the dosage form of Leung, a dosage form which relates to solving an entirely different problem of providing a non-adhering fast-dissolving edible film.

Further, the totality of Hang teaches away and discourages one skilled in the art from the path taken by the applicant, *i.e.*, a consumable film that is rapid-dissolving, and specifically provides rapid transmucosal delivery of nitroglycerin to a patient. Prior art must be considered in its entirety, including disclosures that teach away from the claimed invention. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51 (Fed. Cir. 1983) (the totality of a reference's teachings must be considered). To 'teach away' means that 'a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference or would be led in a direction divergent from the path that was taken by the applicant.' *Monarch Knitting Machinery Corp. v. Sulzer Morat GmbH*, 139 F.3d 877, 885 (Fed. Cir. 1998); *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

As stated above, Hang relates to adding a strengthening polymer to strengthen the thin film and make the film less water soluble--thus detering rapid dissolution of the film. Accordingly, because the general proposition or "totality" of Hang diverges from the path taken by the applicant and effectively teaches away from the claimed compositions including consumable films that are rapid-dissolving and which provide rapid transmucosal delivery of nitroglycerin to a patient.

Also contrary to the Examiner's conclusion, Hang does not teach a composition comprising nitroglycerin, and specifically for rapid transmucosal delivery of nitroglycerin to a patient as presently claimed. Indeed, as stated by the Examiner in an earlier Office Action, "Hang does not teach an embodiment containing nitroglycerin." Office Action mailed March 30, 2010, at page 5. Hang does not provide an example or any embodiment of a thin film that includes nitroglycerin, nor is there any example or embodiment of a thin film that

demonstrates the rapid transmucosal delivery of nitroglycerin to a patient. Further, Leung and Chobanian fail to remedy these glaring deficiencies of Hang as these references do not teach or suggest the limitation of a consumable film which provides rapid transmucosal delivery of nitroglycerin to a patient. Accordingly, Applicant respectfully requests that any rejections of pending claims under 35 U.S.C. § 103(a) over Leung, in view of Hang and Chobanian, or over Hang in view of Chobanian, be reconsidered and withdrawn.

CONCLUSION

The Applicants have properly and fully addressed each of the Examiner's grounds for rejection. Applicants submit that the present application is now in condition for allowance. If the Examiner has any questions or believes further discussion will aid examination and advance prosecution of the application, a telephone call to the undersigned is invited. If there are any additional fees due in connection with the filing of this amendment, please charge the fees to undersigned's Deposit Account No. 50-1067. If any extensions or fees are not accounted for, such extension is requested and the associated fee should be charged to our deposit account.

Respectfully submitted,

/djpelto Reg. No. 33754/

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Don J. Pelto
Reg. No. 33,754

Sheppard, Mullin, Richter & Hampton LLP
1300 I Street NW, 11th Floor East
Washington, DC 20005
Tel: 202-218-0000
Fax: 202-218-0020